K112067

510(k) Summary

SEP 16 2011

SUBMITTER'S INFORMATION

Owner:	Carticept Medical, Inc.
Address:	6120 Windward Parkway, Suite 220, Alpharetta, GA 30005
Phone:	770-754-3800
Fax Numbers:	770-754-3808
Contact Person:	Tanya Eberle, Director, Regulatory Affairs
Date Summary Prepared:	July 18, 2011

DEVICE INFORMATION

Name of Device:	Navigator™ Delivery System (Navigator DS)
Common/Usual Name:	Infusion Pump, External
Classification Name:	Infusion Pump, Class II, 21 CFR 880.5725 (Product Code FRN)
Predicate Device(s):	Navigator™ Delivery System (K101994) Diagnostic Ultrasound Accessory SonoSite M-Turbo and M-MSK, part of the Maxx Series (K082098)
Device Description:	The Navigator Delivery System (Navigator DS) consists of a fluid delivery module, a daily disposable cassette, a per-patient disposable handpiece and tubing set, and wired foot pedal. Image integration with qualified ultrasound units occurs by Ethernet cable connection, if desired, allowing simultaneous display of Navigator treatment information on the ultrasound screen and printing of ultrasound images on the patient treatment record. Qualified ultrasound imaging units include the SonoSite M-Turbo and SonoSite M-MSK, (configuration part numbers L05323 and L05600, respectively).
Indication for Use:	The Navigator™ Delivery System (Navigator DS) is intended for use in the delivery of medication and/or fluids in a controlled manner. The Navigator DS is indicated for use in the intermittent delivery of medications and other fluids in intra-articular applications.
Technological Characteristics:	All technological and design aspects of the Navigator DS device are preserved. Image integration allows simultaneous display of Navigator DS treatment images on

	the ultrasound screen and printing of ultrasound screen images in the patient treatment record. Independent functionality of the Navigator DS device and qualified ultrasound units is preserved.
Comparison to Predicate Devices:	The Navigator DS with the added feature of image integration raises no new questions of safety or effectiveness. The Navigator DS intended use and performance characteristics are not changed by this added feature.
Performance Data:	Testing of the Navigator DS with image integration capability was carried out, included software validation, electrical testing of the connected devices, and simulated use testing. All data demonstrated that the safety and performance of the Navigator DS is not affected by the added ability to interface with ultrasound accessories. A Clinical Evaluation was determined not to be required as the device design, intended use and indication for use are preserved. A Safety Case and Hazard Analysis demonstrated an acceptable risk profile based on design-based risk mitigation and satisfactory performance testing.
Rationale for Substantial Equivalence:	This minor modification allowing imaging integration falls within the FDA regulations for 510(k) review. The Navigator DS with image integration capability is substantially equivalent to the predicate device (Navigator DS K101194).
Conclusion:	The Navigator DS, as modified by this 510(k), does not raise any new issues regarding safety or effectiveness, and therefore is suitable for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tanya Eberle
Director, Regulatory Affairs
Carticept Medical, Incorporated
6120 Windward Parkway
Suite 220
Alpharetta, Georgia 30005

SEP 16 2011

Re: K112067
Trade/Device Name: Navigator Delivery System (or Navigator DS)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: July 18, 2011
Received: July 19, 2011

Dear Ms. Eberle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) No. (if known): K112067

Device Name: Navigator™ Delivery System (Navigator DS)

Indications for Use: The Navigator™ Delivery System (Navigator DS) is intended for use in the delivery of medication and/or fluids in a controlled manner. The Navigator DS is indicated for use in the intermittent delivery of medications and other fluids in intra-articular applications.

Prescription Use: __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/14/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K112067